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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,749	01/14/2002	Michael Vajdy	16464.003	5494

7590 02/23/2004

CHIRON CORPORATION
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,749	VAJDY ET AL.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 11-21, 29 and 30, drawn to a method of generating an immune response against a bacteria by mucosally administering a gene delivery vehicle comprising a polynucleotide encoding an antigen, classified in class 424, subclass 234.1.

If applicant elects this group, applicant is also required to elect a single species of bacterium selected from a-c:

a) Gonorrhea

b) Chlamydia

c) Syphilis

Each of species a-c is distinct for at least the following reasons. First, each species uses a different gene sequence for generating an immune response. Thus, each species uses a different material in performing the method steps. Second, the species are directed to treating their own distinct population in that they each create an immune response to a single divergent bacterial pathogen. Finally, the species produce different results because each antigenic sequence stimulates the production of a distinct antibody.

II. Claims 1-5, 8-21, 29 and 30, drawn to a method of generating an immune response against a virus by mucosally administering a gene delivery vehicle

comprising a polynucleotide encoding an antigen, classified in class 424, subclass 204.1.

If applicant elects this group, applicant is also required to elect a single species of virus selected from d-h:

d) HIV

e) HBV

f) HSV

g) HCV

h) HPV

Each of species d-h is distinct as follows. First, each species is directed to treating a distinct pathogenic virus having different modes of infection and different symptoms. Second, each virus triggers a unique immune response. Accordingly, the immune response triggered by HBV would be ineffective in interacting with HSV, HCV or HPV. The same is also true for the immune responses triggered by HSV, HCV and HPV which would each lack cross-reactivity with the other virus species. For at least these reasons, each of species under Group II is distinct.

III. Claims 1-5, 11-24, 29 and 30, drawn to a method of generating an immune response mucosally by administering a gene delivery vehicle comprising a polynucleotide encoding an antigen and a second gene delivery vehicle encoding a second antigen, classified in class 424, subclass 184.1.

IV. Claims 1-5, 11-21 and 25-30, drawn to a method of generating an immune response mucosally by administering a gene delivery vehicle comprising a polynucleotide encoding an antigen and administering a polypeptide, classified in class 424, subclass 184.1 and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the groups I and II are drawn to eliciting an immune response against different pathogens in different subject populations. Each group requires different ingredients and method steps to compete the goal of each method. Group I is drawn to eliciting an immune response against bacteria while group II is drawn to eliciting an immune response against a virus. The antigens required to elicit an immune response against each pathogen are structurally and functionally divergent. Further, each immune response raised against the specific antigen is specific for the antigen encoded by the delivery vehicle. Therefore, the methods of groups I and II have different functions and effects.

Groups III and IV require different ingredients and methods steps from the methods of groups I and II by requiring a second antigen to be administered. Further, the goal of groups III and IV are drawn to eliciting an immune response against any antigen in any subject population. The method of groups III and IV are distinct from each other because group III requires a second gene delivery vehicle encoding a second antigen and group IV

requires administering a polypeptide in addition to the first gene delivery vehicle. An immune response against a nucleic acid delivery vehicle and a polypeptide are distinctly different. Therefore, groups III and IV have different functions and effects from each other and from groups I and II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper. In addition, issues that may arise in examination of one group may differ.

Claims 1-5, 11-21, 29 and 30 are generic to a plurality of disclosed patentably distinct species comprising gene delivery vehicles and specific immune proteins. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

After applicant has elected groups I-IV (and further elected a bacterial or viral species, if groups I or II are elected), applicant is further required to elect a specific gene delivery vehicle for any group elected, selected from i-l:

i) nonviral vector

j) viral vector

k) particulate carrier

l) liposome preparation

Each gene delivery vehicle species is distinct due to the method of delivery required by each vehicle, method of antigen insertion, antigen capacity and the immune response generated by each vehicle.

If applicant elects species b, viral vector, applicant is further required to elect a specific viral vector selected from:

m) retroviral vector

n) adenoviral vector

Each viral vector is a distinct species because each vector elicits a different immune response, has specificity for different tissues and expresses antigens differently.

After applicant has elected a gene delivery vehicle, applicant is further required to elect a species of immune protein selected from x-z:

x) Class I and/or class II MHC proteins

y) CD3

z) ICAM-1 or LFA-3, or analogues thereof

Species x-z are distinct in that each species uses divergent materials in carrying out the method steps. This results from the fact that the species rely on physically distinct gene sequences for priming and boosting the immune response. Furthermore, the proteins encoded by each gene sequence have distinct functions and properties. Class I and II MHC proteins are histocompatibility genes that are responsible for regulating the immune response of CD4+ and CD8+ T lymphocytes. In contrast, CD3 protein is expressed on the plasma membrane of T lymphocytes where it is associated with T cell receptor. CD3 serves to transmit lymphocyte activation signals. Class I and II MHC proteins are also distinct from the ICAM-1 and LFA-3 gene products. Unlike class I and II MHC proteins, ICAM-1 and LFA-

3 are non-specific structural proteins that are involved in intracellular adhesion. For at least these reasons, species a-d are distinct.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

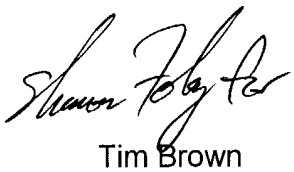
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tim Brown
Examiner
Art Unit 1648

tb